Paper No. 19

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte KENNETH R. JONKMAN

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Appeal No. 2000-2029
Application 09/012,530

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ON BRIEF

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Before CALVERT, FRANKFORT and STAAB, Administrative Patent Judges.

FRANKFORT, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 1 through 10. Claims 11 through 16, the only other claims pending in this application, have been withdrawn from further consideration as being directed to a non-elected invention.

Appellant's invention relates to a dilator for a cannula assembly (claim 6) and to a cannula assembly including such a dilator telescopically received in the lumen of the cannula (claim 1). Independent claims 1 and 6 are representative of the subject matter on appeal and a copy of those claims can be found in the Appendix to appellant's brief.

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:

Toye et al. (Toye)	4,978,334	Dec. 18, 1990
Fonger et al. (Fonger)	5,190,528	Mar. 2, 1993

Claims 6 through 10 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Toye.

Claims 1 through 5 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Fonger in view of Toye.

Rather than reiterate the examiner's full statement of the above-noted rejections and the conflicting viewpoints advanced by the examiner and appellant regarding those rejections, we make reference to the examiner's answer (Paper No. 16, mailed April

10, 2000) for the reasoning in support of the rejections, and to appellant's brief (Paper No. 15, filed January 19, 2000) and reply brief (Paper No. 17, filed June 15, 2000) for the arguments thereagainst.

OPINION

In reaching our decision in this appeal, we have given careful consideration to appellant's specification and claims, to the applied prior art references, and to the respective positions articulated by appellant and the examiner. As a consequence of our review, we have made the determinations which follow.

In rejecting claims 6 through 10 under 35 U.S.C. § 102(b) as being anticipated by Toye it is the examiner's position (answer, page 3), that Toye discloses a dilator (22) with a tapered portion (26) and a generally cylindrical portion (28) located distally of the tapered portion and that the dilator (at 20) is capable of receiving a guide wire and a needle. On page 5 of the answer, the examiner indicates that the part of the dilator seen in Figure 5 of Toye located between portions (26) and (28) where the taper changes to a straight portion is a transition stop and

that such a stop would temporarily halt insertion of the dilator. Appellant argues that Toye does not disclose a dilator for a cannula assembly that is configured to receive simultaneously a needle and a guide wire. In addition, appellant argues that Toye does not disclose a dilator tip that is configured to limit insertion of the needle.

Having reviewed and evaluated the Toye reference, we must agree with the examiner that the dilator (22) seen in Toye anticipates the dilator defined in claim 6 on appeal. Like the examiner, it is our view that the enlarged proximal portion of passage (20) in the dilator (22) of Toye, seen in Figures 2 and 4, is sized and configured to receive simultaneously a needle and a guide wire. We recognize that the Toye patent does not expressly describe or teach that the enlarged proximal portion of passage (20) is actually used to simultaneously receive a needle and a guide wire, but it is apparent to us from the showing in Figures 2 and 4 of Toye that the enlarged proximal portion of passage (20) is clearly capable of such a use and thus is clearly "configured to receive simultaneously a needle and a guide wire," as broadly set forth in appellant's claim 6 on appeal. In this regard, we point out that claim 6 is directed to the structure of

the dilator per se and not to a combination of the dilator with a guide wire and a needle.

As for the recitation in claim 6 that the dilator includes a tip which is "configured to limit insertion of the needle," we agree with the examiner that the dilator of Toye includes a tip structure that is so configured. In reaching this conclusion we have compared Figures 2, 4 and 5 of Toye with appellant's Figures 4 and 5, noting that the dilator tips seen in the present application and in the Toye patent are substantially identical to one another. Each has a distal substantially cylindrical portion (28 of Toye and 40 in the present application) which transitions into an increasing diameter tapered portion (26 of Toye and 38 of appellant's application) and then again transitions into a larger diameter cylindrical portion. In describing the "transition stop" (36) of the present application appellant indicates (specification, page 5) that the dilator tip is "configured such that the dilator tip 32 temporarily stops insertion of the dilator 14 into an incision or puncture site." More specifically, on page 6 of the specification, appellant describes the operation of this aspect of the cannula assembly in the following language

> [t]he cannula assembly 10, with the needle 42 extended through the opening 34 of the dilator tip 32, is advanced to the center of the purse string suture 54. As shown in FIG. 8, the distal end 48 of the needle 42 punctures the aorta, in the center of the purse string suture 54, and the cannula assembly 10 is inserted into the puncture site until the transition stop 36 of the dilator tip 32 contacts the outer wall of the aorta. In the preferred embodiment of the invention, at this stage, only the distal end 48 of the needle 42 and the generally cylindrical portion 40 of the dilator tip 32 are situated in the aorta. By temporarily halting further advancement of the cannula assembly 10 in the aorta, the transition stop 36 is able to control the insertion depth of the needle 42 in the aorta, thereby minimizing the risk of damage to the back wall of the aorta.
>
> Once the cannula assembly 10 has been inserted in the aorta, up to the transition stop 36, the needle 42 is retracted into the passage 30 of the elongate tube 24, and the guide wire 44 is extended through the opening 34 of the dilator tip 32 and into the aorta (FIG. 9). The guide wire 44 facilitates insertion of the cannula 12 in the aorta. The cannula 12 and dilator 14 are then advanced over the guide wire 44 and into the aorta (FIG. 10).

In light of this disclosure, it appears to us that it is the individual who is inserting the dilator tip into the blood vessel who temporarily halts insertion of the cannula assembly when the "transition stop" contacts the outer wall of the blood vessel, rather than the transition stop itself that prevents further insertion of the cannula assembly into the blood vessel. This is particularly true, since after retraction of the needle and

insertion of the guide wire (44) through the opening (34) of the dilator tip, both the cannula (12) and the dilator (14) are then advanced over the guide wire and into the blood vessel. Like the examiner, it is our opinion that the transition region between the cylindrical portion (28) and the tapered portion (26) at the tip of the dilator in Toye is likewise "configured to limit insertion of the needle" therein, at least to the same extent that appellant's tip temporarily does so under manipulation by the individual doing the insertion (i.e., the individual "temporarily halting further advancement of the cannula assembly" into the blood vessel when the transition stop contacts the outer wall of the vessel).

Appellant provides no indication as to exactly how the individual inserting the cannula assembly into a blood vessel knows when the transition stop contacts the outer wall of the vessel. We presume that some form of viewing device allows the individual to see that such contact has occurred or that an increase in resistance to insertion is noticed due to the increasing diameter of the tip at the transition region. Both of these possibilities would also allow one using the dilator in Toye to temporarily halt further advancement of the cannula

assembly/dilator tip into a blood vessel at the transition region of the tip and thereby provide the same form of "stop" described by appellant.

In light of the foregoing, we will sustain the examiner's rejection of independent claim 6 under 35 U.S.C. § 102(b) as being anticipated by Toye. Given appellant's grouping of the claims (brief, page 3) and the lack of any separate argument as to claims 7 through 10, those claims will fall with independent claim 6 from which they depend.

Regarding the examiner's rejection of claims 1 through 5 under 35 U.S.C. § 103(a) as being unpatentable over Fonger in view of Toye, the examiner has indicated that Fonger discloses a cannula assembly substantially as claimed by appellant, except that the structure in Fonger does not have a dilator tip configured in the manner required in claims 1 through 5 on appeal. To provide for that deficiency in Fonger, the examiner points to the teachings of Toye. In the examiner's view

> [b]ecause the two dilators are art-recognized functional equivalents, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the dilator in Toye et al. with the cannula assembly in Fonger et al.

Like appellant, we are of the opinion that the examiner has not made out a proper case of *prima facie* obviousness based on the attempted combination of Fonger and Toye. Having carefully reviewed the applied patents, we see no reason why one of ordinary skill in the art would have viewed the dilator (22) of Toye and the catheter structure (5) of Fonger to be "art-recognized functional equivalents," as is urged by the examiner. Moreover, we see no motivation or suggestion in the applied references, and the examiner has pointed to none, that would have led one of ordinary skill in the art to use the dilator of Toye in the percutaneous transseptal left atrial cannulation system of Fonger. In particular, given the entirely different manner of inserting the cannula (3) of Fonger into the heart and through the septum into the left atrium, we see no reason whatsoever to use the dilator of Toye in Fonger. Thus, since we have determined that the teachings and suggestions that would have

been fairly derived from Fonger and Toye would not have made the subject matter as a whole of claim 1 on appeal obvious to one of ordinary skill in the art at the time of appellant's invention, we must refuse to sustain the examiner's rejection of that claim under 35 U.S.C. § 103(a). It follows that the examiner's rejection of dependent claims 2 through 5 under 35 U.S.C. § 103(a) based on Fonger and Toye will also not be sustained.

In summary, the decision of the examiner rejecting claims 1 through 5 under 35 U.S.C. § 103(a) based on Fonger and Toye is reversed, while the examiner's decision to reject claims 6 through 10 under 35 U.S.C. § 102(b) as anticipated by Toye is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART

IAN A. CALVERT Administrative Patent Judge	)	
CHARLES E. FRANKFORT Administrative Patent Judge	)	BOARD OF PATENT APPEALS AND INTERFERENCES
LAWRENCE J. STAAB Administrative Patent Judge	)	

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